UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address : COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
07/554,904	07/24/90	NAIR	X WW-0041A

EXAMINER
HULINA, A

ART UNIT	PAPER NUMBER
152	5

DATE MAILED: 04/30/91

DAVID M. MORSE
BRISTOL-MYERS SQUIBB COMPANY
P. O. BOX 5100
WALLINGFORD, CT 06492-7660

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☒ Notice re Patent Drawing, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☒ Claims 1-20 are pending in the application.
   Of the above, claims none are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1-20 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____ ; filed on _____.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

15. Claims 1 and 11 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited a retinoid selected from the group consisting of all-trans retinoic acid, (N-acetyl-4-aminophenyl) retinoate, and 11-cis,13-cis-12-hydroxymethyl retinoic acid delta lactone. See M.P.E.P. §§ 706.03(n) and 706.03(z).

The specification is not enabling for a synergistic composition using any retinoid.

16. Claims 1,2,,5,8,11,12,15 and 18 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to a composition containing from 0.1 % to 5 % by weight of 4-hydroxyanisol and from 0.001 % to 1 % by weight of said retinoid . See M.P.E.P. §§ 706.03(n) and 706.03(z).

The specification is not enabling for a synergistic composition using any amounts of 4-hydroxyanisole and a retinoid.

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

18. A person shall be entitled to a patent unless --
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

19. Claims 1,2,3 are rejected under 35 U.S.C. § 102(b) as being anticipated by Marks or Papa.

Marks discloses a composition for topical application containing tretinoin (all-trans retinoic acid) in an amount of

between 0.001-0.5 weight % and an antioxidant such as butylated hydroxyanisole in an amount of between 0.01-0.1 weight % (see examples 1 and 7).

Papa discloses topical compositions containing zinc salts of all-trans retinoic acid in an amount of between 0.001-0.5 weight % and an antioxidant such as butylated hydroxyanisole (col.2, line 21) in an amount of between 0.01-0.1 weight %.

20. The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

21. Claims 1-20 are rejected under 35 U.S.C. § 103 as being unpatentable over Kligman (Canadian patent 982945) in view of Kligman (U.S. Patent 3,856,934).

Kligman (982945) discloses a synergistic composition for skin depigmentation by topical application which is comprised of a mixture of hydroquinone monomethyl ether (4-hydroxyanisole),

retinoic acid and a corticosteroid in a pharmaceutically acceptable vehicle. The hydroquinone is present in an amount of from about 1 to about 5 weight percent of the composition and the retinoic acid is present in an amount of from about 0.025 to about 15 weight percent of the composition.

Kligman (3,856,934) discloses a skin depigmentation composition for topical application comprising hydroquinone, retinoic acid and a corticosteroid. Kligman teaches that the combination of hydroquinone and retinoic acid was ineffective to provide complete depigmentation. Therefore since it is known to make a composition for skin depigmentation containing only hydroquinone and retinoic acid, it would have been obvious to omit the corticosteroid from the compositions of Kligman (982945) containing 4-hydroxyanisole and retinoic acid in order to make a composition where a less strong depigmentation effect was desired. It would also have been obvious to one of ordinary skill in the art to use any retinoid capable of providing an exfoliating effect absent a showing of unexpected results using a particular retinoid.

22. Any inquiry concerning this communication should be directed to Amy Hulina at telephone number (703) 308-2351.

Amy Hulina
April 22, 1991

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
ART UNIT 152